

<b>Notice of Allowability</b>	<b>Application N .</b>	<b>Applicant(s)</b>	
	10/637,886	O'CONNELL ET AL.	
	<b>Examin r</b>	<b>Art Unit</b>	
	Kamal A Saeed	1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address--**  
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. ☐ This communication is responsive to \_\_\_\_\_.
- 2. ☒ The allowed claim(s) is/are 9-16 now 1-8.
- 3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
- 4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    - 1. ☐ Certified copies of the priority documents have been received.
    - 2. ☐ Certified copies of the priority documents have been received in Application No. 10/172,614 .
    - 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
- 5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
- 6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

- 7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 8. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

- 9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 2 <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                               | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ .           |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input type="checkbox"/> Examiner's Amendment/Comment                             |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material           | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|  | 9 <input type="checkbox"/> Other .  |

### ***Reasons For Allowance***

The following is an examiner's statement of reasons for allowance:

The invention relates to a factory scale process for preparing crystalline atrovastatin trihydrate comprising several steps including drying the isolated product in vacuum pan drying with an agitator that is rotated at a speed from 0.5 to 2 rpm. The closest prior art of record is to Briggs et al, U.S. 5,969,156. Briggs et al teach a process for preparing crystalline atrovastatin trihydrate that also comprises of a step of drying the product under vacuum. The process of this application differ from the prior art in that the use of vacuum pan drying with an agitator ensures that the final dried atorvastatin calcium product is within consistent particle size range and bulk density. The prior art does not teach or suggest the process as described in this application.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right)

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~~“Official” for papers that are to be entered into the file, and “Unofficial” for draft documents~~

and other communications with the PTO that are not for entry into the file of the application.

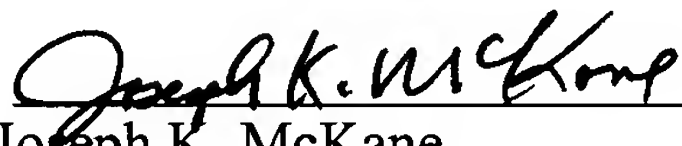
This will expedite processing of your papers.

Art Unit: 1626

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

Kamal Saeed, Ph.D  
December 12, 2003

  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1

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